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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,564	01/27/2004	William Dubrul	GTEC 1001-5	8126
23470	7590	06/13/2008		
HAYNES BEFFEL & WOLFELD LLP			EXAMINER	
P O BOX 366			HOUSTON, ELIZABETH	
HALF MOON BAY, CA 94019				
		ART UNIT	PAPER NUMBER	
		3731		
		MAIL DATE	DELIVERY MODE	
		06/13/2008	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/765,564

Applicant(s)

DUBRUL ET AL.

Examiner

ELIZABETH HOUSTON

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 10-16, 19, 20, 22-25, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6, 7, 10-16, 19, 20, 22-25, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/05/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 03/05/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,238,412, has been reviewed and is accepted. The terminal disclaimer has been recorded.
2. The terminal disclaimer filed on 03/05/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent 6,699,260 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. **Claims 6, 7, 10-16, 19, 20, 22-25, 27 and 28 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Solano et al. (US 4,921,478).**
5. Solano discloses the invention substantially as claimed including an occluder and a method of deploying an occluder that comprises: a catheter having a distal end (Fig.

3), having a balloon-less blood flow blocking element comprising structural members (28) defining openings there between (27) and positioned near the distal end of the catheter, said blood flow blocking element having a radially compressed insertion state and a radially expanded blocking state (figs. 6a, 6d, 10a, 10b), an actuator (22) associated with said catheter to move said blood flow blocking element from said compressed state to said expanded state (Col 5, lines 54-68), the step of radially expanding the blood flow blocking element being carried out without inflating a balloon using a fluid [NOTE: the act of expanding the blocking element (28) is done with actuator (22) and does not require the expansion of the balloon (16,76) (C5: L54-68); additionally, the balloon can be inflated with air as well as fluid (C5: L 30-35)], and said blood flow blocking element in said radially expanded blocking state having an outer distally facing, generally funnel surface extending out from said distal end of said catheter (figs. 6d, 8, 10b). The blocking element blocks passage of material around the outside of the catheter and is a malecot style device. An annular membrane (16,76) that contacts the structural members is an elastomeric impermeable membrane (Col 6, lines 45-56). The actuator (22) extends though the lumen of the catheter (24) distal of said blood flow blocking element and when moved in a proximal direction, engages said blood flow blocking element to switch said blood flow blocking element from said retracted insertion state into said radially expanded blocking state (Col 5, lines 62).

Response to Arguments

6. Applicant's arguments filed 03/05/08 have been fully considered but they are not persuasive. Regarding the limitation of "a balloon-less blood flow blocking element" it is noted that although Solano does include an inflatable membrane (16) around the struts (28), it is the struts alone that are considered the blood blocking element and not the combination of the struts and the balloon. Note that the blood flow blocking element is not required to completely occlude the passage of all blood through the vessel. Regarding the limitation that the "step of radially expanding being carried out without inflating a balloon using a fluid, although Solano does disclose the step of inflating a balloon, it is not the act of inflating the balloon that is radially expanding the blood flow blocking element. The blood flow blocking element is expanded by axial movement of the actuator (22). Additionally, the claims require that the act of expanding not be carried out by inflating a balloon using a fluid, however Solano discloses the use of fluid or gas.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./

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/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731